PB89-126064

Guidance for the Reregistration of Pesticide Products Containing Tetrachlorvinphos as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, Dc

Oct 88

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB89 126064/AS

4. Title and Subtitle Guidance for the Reregistration of Pesticide Products Containing TETRACHLORVINPHOS as the Active Ingredient

5. Report Date October 1988

6.

7. Author(s) EPA, Office of Pesticide Programs Registration Div.

8. Performing Organization Rept. No. 540/RS-89-003

9. Performing Organization Name and Address

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, S.W.
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.

(C)

(G)

12. Sponsoring Organization Name and Address

Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manfacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Publicly Available

19. Security Class (This Report) Unclassified

20. Security Class (This Page) Unclassified

21. No. of Pages 123

22. Price

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

540/RS-89-003
October 1988

Pesticides

PB89-126064

EPA

Guidance for the Reregistration of Pesticide Products Containing TETRACHLORVINPHOS as the Active Ingredient

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL INFORMATION SERVICE
SPRINGFIELD, VA. 22161

OMB Control No. 2070-0057
Expires November 1989

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

TETRACHLORVINPHOS

AS THE ACTIVE INGREDIENT

[0321]

CAS No.961-11-5

October 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

TABLE OF CONTENTS

I. Introduction 1

II. Chemical(s) Covered by this Standard 3
    A. Description of Chemical
    B. Use Profile

III. Agency Assessment 6
    A. Introduction
    B. Health Risk Assessment
    C. Ecological Effects
    D. Environmental Fate
    E. Reported Pesticide Incidents
    F. Tolerance Reassessment
    G. Summary of Data Gaps

IV. Regulatory Position and Rationale. 17
    A. Regulatory Positions
    B. Criteria for Registration
    C. Acceptable Ranges and Limits
    D. Required Labeling

V. Products Subject to this Standard 27

VI. Requirement for Submittal of Generic Data 29
    A. What are generic data? . . . .
    B. Who must submit generic data? . . . .
    C. What generic data must be submitted?. . . . . .
    D. How to comply with DCI requirements . . . . . .
    E. Registrant requests regarding data requirements and Agency responses . . . .
    F. Test protocols and standards . . . .
    G. Procedures for requesting a change in protocol.
    H. Procedures for requesting extensions of time
    I. Data Format and Reporting Requirements. . . . .
    J. Existing stocks provisions upon suspension or cancellation . . . .

VII. Requirement for Submittal of Product-Specific Data . . 36

VIII. Requirement for Submittal of Revised Labeling 37

IX. Instructions for Submittal. 38
    A. Manufacturing use products (sole active)
    B. Manufacturing use products (multiple active)
    C. End use products (sole active)
    D. End use products (multiple active)
    E. Intrastate Products

APPENDICES

I. DATA APPENDICES 42

- Guide to Tables 43
- Table A
- Table B
- Table C

II. LABELING APPENDICES 74

- Summary of label requirements and table
- 40 CFR 156.10 Labeling Requirements
- Physical/Chemical Hazards Labeling Statements
- Storage Instructions
- Pesticide Disposal Instructions
- Container Disposal Instructions

III. BIBLIOGRAPHY APPENDICES 98

- Guide to Bibliography
- Bibliography 99

IV. FORMS APPENDICES 109

EPA Form 8580-1	FIFRA 3(c)(2)(B) Summary Sheet
EPA Form 8580-3	Generic Data Exemption Statement
EPA Form 8580-4	Product Specific Data Report
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System

NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
OES	Office of Endangered Species, U.S. Fish and Wildlife Service
PADI	Provisional Acceptable Daily Intake
ppm	Parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,[1] focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV -

---

[1] The scientific reviews and Compendium of Uses may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Telephone (703) 487-4650.

Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard.

Common Name: Tetrachlorvinphos

Generic Name: (Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate

Other Chemical Names: (Z)-2-chloro-1-(2,4,5-trichloro-phenyl) ethenyl dimethyl phosphate

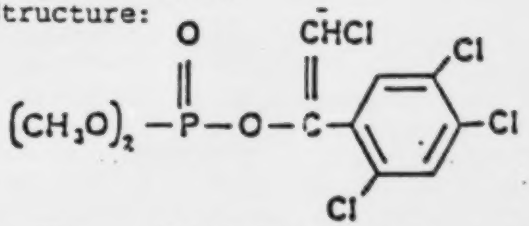
Trade Names: Stirofos, Gardona, Rabon, CVMP, Gardcide.

Chemical Class: Organophosphate

Empirical Formula: $C_{10}H_9Cl_4O_4P$

Molecular Weight : 366.0

Molecular Structure:



CAS Registry NOs.: 22248-79-9 [(Z) -isomer]
22350-76-1 [(E) -isomer]
961-11-5 (mixed isomers)

OPP Shaughnessy No.: 083701

Year of Initial Registration: 1966

U.S. and Foreign Producers: E.I.duPont de Nemours & Co. and Fermenta Animal Health Co. (Animal Health Products).

Physical/chemical properties of tetrachlorvinphos

Color: tan to brown

Physical State: solid

Odor: mild chemical

Melting Point: 93-98 C

Boiling Point: N/A - solid at room temperature

Bulk Density: 50-55 lb/cu ft

Solubility: 15 ppm in water at 24°C; 40 ppm in chloroform, 40 ppm in dichloromethane, 20 ppm in acetone, and 8 ppm in xylene at 0°C

B. Use Profile

Type of Pesticide: Non-systemic organophosphate

Pests Controlled: Fleas, lice, ticks, ants, chiggers, mites, itch mite family, chicken mite, northern fowl mite, filth and manure flies (face fly, horn fly, house fly, and stable fly), deer fly, spiders, wasps, gnats, mosquitoes, and cockroaches.

Registered Uses: Terrestrial nonfood crop use on recreational areas; Domestic outdoor use on domestic premises; Indoor use in/on livestock (beef and dairy cattle, swine, horses, and ponies), poultry, mink, farm animal buildings, pets (cats and dogs), pet living quarters, domestic dwellings, and garbage dumps.

Principal Uses: The major use is for controlling filth or manure flies associated with livestock (cattle, swine, horses, mink) and is applied in the form of mineral blocks and feed additives. Remaining uses include dusts, wettable powders and sprays applied to agricultural premises, livestock, pets and flea collars. Tetrachlorvinphos impregnated ear tags comprise a small amount of the formulated a.i.

Mode of Application: contact and stomach poison

Method of Action: Premise treatment by conventional hydraulic sprayer or low pressure knapsack; animal treatment by hand dusting (shaker can, hand duster, grooming brush, dust mitt), pressurized spray, flea collars, ear tags, dust bags, oral feed additive, oral mineral block, backrubber.

Formulations: Dust, granular, pelleted/tableted, wettable powder, wettable powder/dust, impregnated material, emulsifiable concentrate, ready-to-use and pressurized liquid.

Basic Producers: E.I. dupont de Nemours & Co.
Fermenta Animal Health Co.
(livestock products)

Annual Usage: approximately 500,000 lbs. a.i.

III. AGENCY ASSESSMENT

A. INTRODUCTION

The Agency has reviewed all data in Agency files as of December 17, 1988 supporting the registration of tetrachlorvin phos. Data received by the Agency after this date have not been reviewed for the purposes of this standard. This section discusses the Agency's scientific findings and conclusions based on these data.

B. HEALTH RISK ASSESSMENT

The Agency has reviewed tetrachlorvinphos data in the areas of acute toxicity, subchronic and chronic toxicity, oncogenicity, reproductive effects, mutagenicity, environmental fate and exposure, and ecological effects. The following assessment is based on available data.

1. Acute Toxicity

No data are available on the acute oral and dermal toxicity, primary eye irritation, primary dermal irritation or sensitization properties of tetrachlorvinphos. Technical tetrachlorvinphos is not very toxic on an acute inhalation basis. It is in Toxicity Category III for inhalation exposure based on an acute inhalation toxicity value (LC_{50}) of >3.61 mg/L (expressed in gravimetric concentration) in male and female Sprague-Dawley rats. Sufficient data are available on the acute delayed neurotoxicity of tetrachlorvinphos. In hens, it was reported that as a single oral (capsule) dose of 1.5 g/kg or as multiple oral doses of 300 mg/kg/day for five days, tetrachlorvinphos did not produce clinical signs of neurotoxicity.

2. Subchronic Toxicity

Data are available to assess the subchronic oral toxicity of tetrachlorvinphos. In a subchronic oral toxicity study in which dogs (3 male and 3 females per treatment group) were fed diets containing 50, 200, 800, or 3200 ppm (1.25, 5, 20, or 80 mg/kg) of tetrachlorvinphos the major treatment-related effects were:

(1) statistically significant decrease in hemoglobin and erythrocytes in male dogs of the high-dose group indicating normocytic anemia; and (2) statistically significant decrease in plasma cholinesterase activity in male and female animals of the 800 ppm (80 mg/kg) and 3200 ppm (80 mg/kg). The NOEL was 200 ppm (5mg/kg) in both sexes for cholinesterase inhibition.

In a subchronic oral toxicity study in which rats (15 male and 15 females) were fed diets containing 12.6, 50, 200, 800, or 3160 ppm (0,63, 2.5, 10, 40, or 158 mg/kg) of tetrachlorvinphos, statistically significant depression in plasma cholinesterase was seen in both sexes of the 800 ppm (40 mg/kg) and 3160 ppm (158 mg/kg) groups. Liver and kidney weights were higher in both sexes of the high-dose group. In female rats, terminal body weight and hemoglobin was lower in the 800 (40 mg/kg) and 3160 ppm (158 mg/kg) groups compared to controls. The NOEL was 200 ppm (10 mg/kg) in both sexes for cholinesterase inhibition. Both the rat and dog subchronic oral toxicity studies are considered to be supplementary by the Agency because the purity and stability of tetrachlorvinphos used was not specified. However, since the Agency has acceptable rat and dog chronic feeding studies that suffice to characterize subchronic effects, subchronic oral toxicity studies are not required. A 90-day neurotoxicity study is not required, since the acute neurotoxicity was negative in hens.

3. Developmental Effects

Based on an acceptable rabbit teratology study, in which eighteen New Zealand White rabbits were administered orally (by gavage) tetrachlorvinphos at dose levels of 0, 150, 375, or 750 mg/kg on days 6 through 19 of gestation, tetrachlorvinphos was not teratogenic. Soft tissue variations and skeletal malformations were comparable between the treated and control groups. The number of viable fetuses per litter was reduced at the middle (375 mg/kg) and high (750 mg/kg) dose groups compared to controls. Maternal toxicity was seen in the high dose group in the form of reddish vaginal discharge. The fetotoxic No Observable Effect Level (NOEL) is 150 mg/kg based on a decrease in number of viable fetuses and the maternal NOEL is 375 mg/kg based on reddish vaginal discharge. A second teratology study in a species other than the rabbit is required.

4. Reproduction

Sufficient data are available to assess the potential effects of tetrachlorvinphos on reproduction. In a rat reproduction study in which rats (20 female and 10 males per group) were fed diets containing 0, 100, 333, or 1000 ppm (0,5,16.7, or 50 mg/kg) of tetrachlorvinphos over a period of three generations, the only compound related effect seen was the increase in liver size in the F_{3b} weanlings in the 50 mg/kg group. No other compound-related effects were seen in the parents or the litters. A NOEL of 16.73 mg/kg (333 ppm) (for increased liver size in F_{3b} weanlings) has been established.

5. Metabolism

Preliminary data indicate that tetrachlorvinphos is completely metabolized in dogs and rats and excreted mainly in the urine and to a lesser extent in the feces as metabolites. Six metabolites were identified and quantified from rat urine and four metabolites from dog urine. All metabolites in dog urine were common to those in rat urine but were quantitatively different. These studies are inadequate to fully characterize the metabolism of tetrachlorvinphos due to reporting deficiencies and design flaws.

6. Mutagenicity

There are no acceptable mutagenicity studies on tetrachlorvinphos. Studies in all three categories (gene mutation, structural chromosome aberrations and other genotoxic tests) are required. Tetrachlorvinphos was positive in a dominant lethal assay, resulting in the decreased rate of pregnancies and number of fetal implants in mice. However, no compound related effects were seen in an *in vivo* bone marrow assay (Chinese hamsters) or in a host-mediated (mouse) assay with microorganisms. These studies are considered by the Agency to be inadequate due to design and reporting flaws, and a full battery of studies is required.

7. Chronic Toxicity

Cholinesterase inhibition and reduced weight gains are the significant toxic effects resulting from chronic exposure to tetrachlorvinphos. This is based on an acceptable chronic feeding dog study, in which tetrachlorvinphos was administered in the diet to six beagle dogs (3 males and 3 females) at 0, 5, 25, 125, and 2000 ppm (0, 0.13, 0.63, 3.13, or 50 mg/kg) for 2 years. Effects considered to be compound-related were observed at the highest dose tested (50 mg/kg). These effects included a significant decrease in plasma cholinesterase activity and a significant increase in the relative liver and kidney weights in both sexes. Based on this, the No-Observable Effect Level (NOEL) is 3.13 mg/kg (125 ppm).

Based on an acceptable chronic toxicity study in the rat, a NOEL of 6.25 mg/kg (125 ppm) is established for the effects of cholinesterase inhibition and reduced weight gain. In this study, male and female rats were fed diets containing 0, 5, 25, 125, or 2000 ppm (0, 0.25, 1.25, 6.25, or 100 mg/kg) of tetrachlorvinphos for 2 years. A total of 60 male and 60 female rats were used for the control group; 40 rats/sex for the 5, 25, or 125 ppm (0.25, 1.25, or 6.25 mg/kg) groups; and 20 rats/sex for the 2000 ppm (100 mg/kg) group. Compound-related effects were seen only in the high-dose group (100 mg/kg) and consisted mainly of significantly decreased body weights in both sexes, significantly decreased plasma cholinesterase activity in male rats, and plasma and erythrocyte cholinesterase activity in females.

8. Oncogenicity

Based on the Agency's Guidelines for Carcinogen Risk Assessment, the Agency has classified tetrachlorvinphos as a Group C (i.e. possible human) carcinogen, with a cancer potency estimate (Q_1^*) of 3.1×10^{-3} $(mg/kg/day)^{-1}$.

The Agency's decision to classify tetrachlorvinphos as a Group C carcinogen is based on a finding of significant increases in hepatocellular adenomas/carcinomas and kidney adenomas/carcinomas in mice. In rats, there was an increased incidence of thyroid and adrenal cortical adenomas; however, the study is considered by the Agency to be equivocal and another oncogenicity study in the rat must be submitted. A synopsis of these studies is provided below.

Mouse Study (Hazleton Laboratories). Tetrachlorvinphos was administered in the diet to groups of 80 male and 80 female B6C3F1 mice at 0, 17.5, 64, 320, 1600, 8000, or 16,000 ppm (0, 2.6, 9.6, 48, 240, 1200, or 2400 mg/kg) for 103 weeks. Control groups consisted of 160 mice/sex.

In male mice, there was a statistically significant increase in hepatocellular adenoma/carcinoma combined, at 16,000 ppm (2400 mg/kg) (Highest Dose Tested) with a statistically significant trend. In female mice, there was a statistically significant increase in hepatocellular carcinomas at 8000 (1200 mg/kg) and 16,000 ppm (2400 mg/kg), and in combined adenoma/carcinoma at 1600 (240 mg/kg), 8000 (1200 mg/kg), and 16,000 ppm (2400 mg/kg); adenomas were statistically increased at 16,000 ppm (2400 mg/kg), only; there was a statistically significant trend for adenoma, carcinoma and for combined adenoma/carcinoma, as well.

In male mice only, there was also a statistically significant increase in renal adenoma, carcinoma and adenoma/carcinoma, combined, at 16,000 ppm (2400 mg/kg); there was also a statistically significant trend for adenoma, carcinoma and for combined adenoma/carcinoma, as well.

The Agency has determined that the Maximum Tolerated Dose (MTD) was achieved or slightly exceeded in this study at the 8000 ppm (1200 mg/kg), based on body weight gain depression (>15%). There was no significant histopathology at 8000 ppm (1200 mg/kg), but significant histopathology at 16,000 ppm (2400 mg/kg), indicative of cellular proliferation (severe liver necrosis) was present. The liver necrosis was not life-threatening, however, as survival at this dose (16,000 ppm) was actually enhanced compared to controls.

Mouse study (Gulf South). In this study, tetrachlorvinphos was administered in the diet to groups of 50 male and 50 female B6C3F1 mice at 0, 8000 or 16,000 ppm (0, 1200, or 2400 mg/kg) for 80 weeks (with an additional observation period of 12 weeks). Matched controls (0 mg/kg) consisted of 10 untreated mice/sex; pooled controls were from bioassays of 4 other test chemicals (40 males and 40 females).

In male mice there was a statistically significant increase in hepatocellular carcinoma at both dose levels, with a statistically significant trend. There was also a liver lesion, designated as a neoplastic nodule which was statistically significant in males, at the low dose only, and in females at both doses with a statistically significant trend. The Agency has determined that the MTD was achieved or slightly exceeded at 8000 ppm (1200 mg/kg).

Rat Study (Gulf South). In this study, tetrachlorvinphos was administered in the diet to groups of 50 male and 50 female Osborne-Mendel rats at 0, 4250, or 8,500 ppm (0, 212.5, or 425 mg/kg) for 80 weeks (with an additional observation period of 31 weeks). Matched controls (0 mg/kg) consisted of 10 untreated rats/sex; pooled controls were from bioassays of 4 other test chemicals (45 males and 45 females).

In female rats there was a statistically significant increase in thyroid c-cell adenoma at 8500 ppm or 425 mg/kg (HTD), with a statistically significant trend. There was also a statistically significant increase in adrenal cortical adenoma at the HTD, with a statistically significant trend. Male rats did not show treatment related increases in either of these tumors.

Oncogenic Potency

The oncogenic potency (Q_1^*) was calculated based on data in the 103-week dietary study on B6C3F1 mice conducted by Hazelton Laboratories (the liver tumor (carcinoma and/or adenoma) in female mice illustrates the most sensitive outcomes with dose increments of the chemical). The highest dose (16,000 ppm or 2400 mg/kg) was excluded from the calculations because the Agency determined that the Maximum Tolerated Dose (MTD) was exceeded at this level. The Q_1^* in animal units $(mg/kg/day)^{-1}$ was converted to human equivalents by means of an interspecies surface area adjustment as recommended by the Agency's Carcinogen Risk Assessment Guidelines to account for the difference in body weight and surface area. The estimated unit oncogenic potency factor, Q_1^*, in human equivalents for this chemical is 3.1×10^{-3} $(mg/kg/day)^{-1}$.

RISK ASSESSMENT FOR ONCOGENICITY AND CHRONIC EFFECTS

1. Dietary Non-Oncogenic Risk

Dietary exposure to tetrachlorvinphos residues may occur as a result of its use on livestock. Published tolerances exist for residues of tetrachlorvinphos on meat, milk, and eggs (40 CFR 180.252). The Theoretical Maximum Residue Contribution (TMRC) is 0.0015 mg/kg/day for the U.S. population average. The TMRC assumes that all meat, milk and eggs contain residues at the maximum level and that 100% of the site is treated. The Provisional Acceptable Daily Intake (PADI) was calculated to be 0.03 mg/kg/day based on a 2-year dog feeding study with a No Observable Effect Level (NOEL) of 3.13 mg/kg (125 ppm) for the effect of increased relative liver and kidney weights. The Uncertainty Factor applied was 100 in calculating the PADI to account for inter-and intraspecies differences (ADI x 100 = NOEL). The TMRC for the U. S. population average occupies between 2.0 % (low) and 10 % (high) of the PADI. In no population group analyzed did the TMRC equal or exceed the PADI.

2. Dietary Oncogenic Risk

Using the Q_1^* of 3.1 x 10-3 mg/kg/day$)^{-1}$ and the TMRC, the dietary oncogenic risk is calculated as follows:

$$\text{Risk} = \text{Exposure} \times Q_1^*$$

$$= 0.0015 \times 0.0031$$

$$= 4.7 \times 10^{-6}$$

This dietary risk assessment is most likely overestimated, since it assumes that all meat, milk and eggs contain residues at the tolerance level. The Agency has no data on which to adjust theoretical maximal residues (such as extent of actual usage and processing effects). However, from 1972-1985, no tetrachlorvin phos residues were found in livestock (cattle, sheep, goats, swine, horses, poultry) samples analyzed in USDA's National Residue Monitoring Program. Both the oncogenic and non-oncogenic risks are considered to be worst-case estimates.

3. Non-Dietary Oncogenic Risk

Non-dietary exposure to mixer/loaders and/or applicators can result from the application of tetrachlorvinphos to livestock, pets, and agricultural premises. Limited data are available regarding likely non-dietary exposure resulting from these uses.

Thus, the Agency will require such exposure data for representative uses of tetrachlorvinphos in order to assess the risks from mixing/loading and/or applying the pesticide. The following use patterns must be monitored during mixing/loading and /or application of tetrachlorvinphos for both dermal and inhalation exposure : feed additive, general indoor and outdoor sprays (one site each), poultry house spray, and large animal dusts. Moreover, since the Agency has no data on dermal absorption of tetrachlorvinphos, a dermal penetration study is required.

C. ECOLOGICAL EFFECTS

The available studies show that tetrachlorvinphos is practically non-toxic to avian species, but is highly toxic to coldwater and warmwater fish. No studies are available for evaluation of hazard to freshwater aquatic invertebrates from the use of tetrachlorvinphos and are being required. A discussion of the ecological effects is set forth below.

1. Terrestrial Organisms

Tetrachlorvinphos is practically non-toxic to birds as demonstrated by both acute and dietary studies. Acute oral tests with mallards, pheasant, and chukars resulted in LD50's of >2,000 mg/kg. Dietary studies with mallard, japanese quail, and ring-necked pheasant resulted in LC50's of >5,000 ppm.

2. Aquatic Organisms

Available acute test results indicate that tetrachlorvinphos is highly toxic to fish. Acute tests resulted in LC50's of 0.43 ppm to rainbow trout and 0.53-1.0 ppm to bluegill sunfish.

3. Non-target Insects

Data from honey bee acute contact toxicity studies indicate that tetrachlorvinphos is highly toxic to honey bees (contact LD50 = 1.37 ug/bee), when bees are exposed to direct treatment. However, toxicity of foliar residues is short-lived, with bee hazard minimal after three hours.

4. Endangered Species

There are sufficient data to indicate that the currently registered domestic indoor and outdoor uses of tetrachlorvinphos are not expected to result in significant concentrations in the habitat of susceptible aquatic and terrestrial organisms. Thus, there is no expected risk to endangered species.

D. ENVIRONMENTAL PROFILE

Available data are insufficient to fully assess the environmental fate of tetrachlorvinphos.

Preliminary findings from an aerobic soil metabolism study indicate that under aerobic conditions, 14C tetrachlorvinphos,at 13.4 ppm, degraded with a half-life of <8 days in medium loam soil. The major degradates were identified as 1-(2,4,5-trichlorophenyl)-2-chloroethan-1-ol and 1-(2,4,5,-trichlorophenyl)ethan-1-ol. 1-Chloroacetyl-2,4,5-trichlorobenzene, 2,4,5-trichloraceto-phenone, and 1-(2,4,5-trichlorophenyl)ethane-diol were also detected. However, this study was not adequate to fully characterize the aerobic soil metabolism of tetrachlorvinphos primarily because the soil was not typical of U. S. soils. There were also deficiencies in the conduct and reporting of the study.

E. REPORTED PESTICIDE INCIDENTS

As part of its assessment of tetrachlorvinphos, the Agency reviewed its Pesticide Incident Monitoring System data base covering a period from 1981 to December 1986. No deaths have been reported in the U. S. or California due to tetrachlorvinphos. A national survey of 12 percent of the nations' hospitals found two observed occupational poisonings from 1974 to 1976, or an estimated five hospitalized cases per year in the U.S. California, which requires mandatory reporting of all physician-treated, occupationally-related cases, has not reported any incidents of tetrachlorvinphos illness from 1981 through 1986.

During the time period January 1, 1987 to September 1, 1988, the National Animal Poison Control Center at the University of Illinois reorded 43 calls concerning potential tetrachlorvinphos poisoning. Of the 43 calls, 24 involved cats, 13 involved dogs, 4 involved cattle and one each occurred in a horse and a ferret. Evidence of poisoning was strongest in cats and dogs which developed symptoms after exposure to flea and tick preparations including powders, sprays, and collars. The horse case was judged a doubtful poisoning.

F. TOLERANCE REASSESSMENT

Tolerances for residues of the insecticide tetrachlorvinphos in or on various raw agricultural commodities are currently expressed in terms of tetrachlorvinphos per se (40 CFR 180.252). A feed additive regulation has also been established for tetrachlorvinphos per se in Section (40 CFR 186.950). Tolerance revocation procedures (40 CFR 180.7) will be initiated for apples, field corn, sweet corn and popcorn, fresh corn forage and fodder alfalfa, cherries, cranberries, peaches, pears, and tomatoes, since tetrachlorvinphos is no longer registered for these uses.

The Agency has evaluated the residue chemistry and toxicology data supporting the tolerances on animal commodities and has determined that it does not have sufficient data to support the currently established tolerances for residues of tetrachlorvinphos in the fat of cattle, goats, hogs, horses, sheep, and in poultry; in eggs and milk fat, including negligible residues in whole milk. The Agency will complete a reassessment of the established tolerances for tetrachlorvinphos after the required residue and toxicological data are submitted and evaluated.

1. Residue Data

Currently, no tetrachlorvinphos end-use products are registered for use on any plant commodity; therefore, the metabolism of tetrachlorvinphos in plants will not be discussed in this Standard. The nature of the residue of tetrachlorvinphos in animals is not adequately understood because the available data pertaining to metabolism in ruminants and poultry do not include adequate characterization of residues and data were not submitted reflecting direct animal treatments.

The available data, although inadequate, indicate that 14C-residues and 32P-residues of tetrachlorvinphos will occur in the tissues of ruminants and poultry following ingestion of feeds containing [14C]-or [32P]- tetrachlorvinphos.

Data gaps exist for animal metabolism, analytical method validation data, storage stability, as well as the adequacy of multiresidue procedures. On receipt of the data requested in these sections of the Registration Standard, the Agency will assess the adequacy of tolerances for residues in animal commodities.

Adequate gas liquid chromatographic (GLC) analytical methods are available for data collection and enforcement pertaining to residues of tetrachlorvinphos and its low melting isomer SD 13462 in animal commodities and milk. However, the adequacy of the analytical methods for data collection and enforcement may change upon receipt of the required animal metabolism data. If metabolites of concern other than tetrachlorvinphos, per se, are found in the required metabolism studies, adequately validated methods for their detection, which may be used for data collection and tolerance enforcement, will be required.

There are no Canadian or Mexican tolerances and no Codex MRL has been established for tetrachlorvinphos residues in poultry fat and eggs. Therefore, no compatibility questions exist with respect to the Codex MRL.

2. Toxicology Data

The available toxicity data are sufficient for the Agency to calculate a Provisional Acceptable Daily Intake (PADI) for tetrachlorvinphos (0.03 mg/kg/day) based on a 2-year dog study and using an uncertainty factor of 100. The PADI and TMRC (0.0015 average mg/kg/day) will be reassessed when the data required in the Standard have been received and reviewed.

G. Other Science Findings (Product Chemistry)

The Agency has noted that tetrachlorvinphos may be contaminated with tetra- through heptahalogenated dibenzo-p-dioxins or dibenzofurans. Certain polyhalogenated dibenzo-p-dioxin or dibenzofuran congeners have been found to be mutagenic, oncogenic, teratogenic and to cause reproductive toxicity. Nitrosamines have been found to be oncogenic. Analytic data to identify and quantify tetra-through heptachlorinated dibenzo-p-dioxin or dibenzofuran contaminants were required in a Data Call-in Notice issued in June, 1987.

H. Summary of Data Gaps for Tetrachlorvinphos

(Refer to Appendix I, Data Tables, for detailed information and due dates).

Product Chemistry--- All

Residue Chemistry--- Metabolism Studies in Livestock
Residue Analytical Methods (animal residues)

Magnitude of the Residues in Fat of Livestock

Storage Stability

Environmental Fate---Hydrolysis
Photodegradation (in water)
Metabolism Studies (aerobic soil)
Mobility Studies (leaching and absorption/desorption)
Dissipation Studies (soil)
Dissipation of Residues in Excrement

Toxicology--- Acute Oral (rat)
Acute Dermal (rat)
Eye Irritation (rabbit)
Dermal Irritation (rabbit)
Dermal Sensitization (guinea pig)
Domestic Animal Safety
21-Day Dermal
Oncogenicity (rat)
Teratology (rat)
Mutagenicity

Ecological Effects--Acute Toxicity to Freshwater Invertebrates

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on tetrachlorvinphos, the Agency has made the following determinations:

1. Special Review

The Agency is not initiating a special review for tetrachlorvinphos at this time.

Rationale: Although the Agency has classified tetrachlorvinphos as a Group C oncogen (Possible Human Carcinogen), anticipated dietary exposure to humans and the associated risk is not high (10 -6). In addition the exposure analysis and oncogenic risk assessment assume tolerance level residues would be present. Since processing data or the extent of tetrachlorvinphos usage have not been used to estimate the actual residue levels and since pesticide residues on foods as eaten are often considerably lower than the tolerances, the estimate of exposure and oncogenic risk (10-6) would be considered a worst case estimate. The Agency is concerned that potential non-dietary exposure to mixer/loaders and/or applicators resulting from the feed additive, agricultural premise, and general indoor/outdoor uses of tetrachlorvinphos may lead to an oncogenic risk of regulatory concern. The Agency is unable to conclude at the present time that the oncogenic risk criteria of 40 CFR 154.7 have been met. Therefore, the oncogenicity risks of tetrachlorvinphos will be reassessed upon receipt and evaluation of required exposure studies, rat oncogenicity study, and dermal penetration study.

2. Restricted Use

The Agency is not requiring the classification of any of the uses of tetrachlorvinphos as restricted use at this time.

Rationale: Section 3(d)(1)(C) of FIFRA provides that some or all uses of a pesticide will be classified for restricted use if the Administrator determines that without such restriction the pesticide "may generally cause unreasonable adverse effects in man or the environment." The Agency has determined that based upon currently available data, tetrachlorvinphos does not meet any of the risk criteria of 40 CFR 152.170 and therefore, products containing tetrachlorvinphos do not warrant restricted use classification at this time. However, exposure to applicators for certain uses may pose risks of regulatory concern.

Upon receipt and evaluation of required exposure studies and a dermal penetration study the Agency will reassess the requirement for restricted use classification.

3. Domestic Animal Safety

The Agency will analyze the safety and efficacy data of tetrachlorvinphos powders, sprays, flea and tick collars, as well as the feed additive uses to determine if further regulatory action is warranted.

Rationale: Complaints of animal poisoning incidents have been reported relating to the use of tetrachlorvinphos. It has been alleged that tetrachlorvinphos causes illness in dogs, cats, and horses. It is uncertain if these incidents were due to misuse, animal stress (heat, exercise), or age or type of dog and cat or horse treated. As with other organophosphates, tetrachlorvinphos can inhibit plasma and erythrocyte cholinesterase activity in animals. Therefore, existing data submitted in support of tetrachlorvinphos use on animals will be analyzed to determine if the minimum effective rate is being recommended and if it demonstrates an adequate safety margin to animals over its use level. If the data do not demonstrate an adequate margin of safety to animals when used as directed, further regulatory actions may be warranted, including labeling directions, use restrictions or cancellation.

4. Endangered Species Concerns

The Agency is not requiring endangered species restrictions at this time.

Rationale: The indoor/domestic outdoor uses of tetrachlorvinphos are not toxic to plants and are relatively nontoxic to avian wildlife. As a result of these use patterns the products are not expected to enter the habitat of susceptible aquatic and terrestrial organisms in significant concentrations. Because of the apparent lack of exposure of susceptible nontarget organisms, products registered for indoor and domestic outdoor uses are not expected to pose a risk to endangered species.

5. Nontarget Organism Labeling

In order to comply in part to the statutory standard for continued registration, the Agency has determined that tetrachlorvinphos products must bear revised and updated labeling for hazards to nontarget organisms. The specific statements are given Section IV. B of this Standard.

Rationale: Available data show that tetrachlorvinphos is highly toxic to fish. Precautionary label statements relative to the potential risks posed by tetrachlorvinphos to nontarget organisms will provide useful information to promote practices to limit such exposure of nontarget species to this pesticide.

6. Groundwater Concerns

Groundwater and drinking water monitoring are not required for tetrachlorvinphos at this time.

Rationale: There are no available environmental chemistry studies with which to adequately assess the groundwater contamination potential of tetrachlorvinphos. Data for assessing this potential have been required in this Standard.

7. Reentry Requirements

The Agency is not imposing any reentry statements nor is requesting that reentry data be submitted.

Rationale: There are no currently registered uses of tetrachlorvinphos (i.e. outdoor agricultural uses) applied to crops which utilize hand labor tasks.

8. Protective Clothing

The Agency is requiring protective clothing for workers or other users who mix, load, and/or apply tetrachlorvinphos products.

Rationale: Tetrachlorvinphos has been classified by the Agency as a C(Q*1) (possible human) oncogen. For this reason protective clothing is necessary to reduce worker exposure during mixing, loading, and/or applying this pesticide. The precautionary labeling statements provide specific guidance for persons handling tetrachlorvinphos and describe the protective clothing required for handling/applying particular tetrachlorvinphos products.

9. Environmental Fate Labeling

The Agency is requiring data to show the maximum concentration of tetrachlorvinphos and its degradation products in livestock manure at the time such materials are applied to crops as fertilizer. In the interim, labeling restrictions are being imposed until the required data is submitted and reviewed by the Agency.

Rationale: Currently there are no registered uses of tetrachlorvinphos on food crops. By definition, the use of tetrachlorvinphos as a feedthrough for fly control must result in adequate residues being present in fresh manure to inhibit fly development. The rate of decline of these residues in the manure is not known and this use could potentially result in residues of tetrachlorvinphos being present in or on food crops if the manure is applied to the land used to grow food crops.

10. Tolerance Revocation

The Agency will revoke tolerances for alfalfa, cherries, cranberries, apples, corn, peaches, pears, and tomatoes.

Rationale: Currently, there are no registered products bearing these uses. Available data are insufficient to support these tolerances.

11. Tolerances and Significant New Uses[2]

The Agency will not grant any new tolerances or any significant new food uses for tetrachlorvinphos until the required residue chemistry and toxicology data have been submitted and reviewed.

Rationale: The Agency needs additional residue and animal metabolism data in order to characterize the nature of residues in animals. The Agency also needs method validation, storage stability, and teratology data before it can perform a tolerance reassessment for tetrachlorvinphos.

12. Food/Feed Additive Regulations

The Agency will not establish any new food or feed additive regulations pursuant to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and is deferring action on previously established food/feed additive regulations.

Rationale: The Delaney Clause in Section 409 of the FFDCA bars the establishment of food/feed additive regulations for substances which induce cancer in man or test animals, with certain exceptions. The Agency is currently developing a position regarding the Delaney Clause and FIFRA. Once this policy has been established, the Agency will determine what action is required for pesticides which have produced oncogenic responses in animals.

---

[2] "NEW USES" is defined in 40 CFR 152.3 (p). In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TRMC) of greater than 1%.

13. Dioxin/Furan Contamination

The Agency is requiring analytical chemistry data for tetrachlorvinphos products to evaluate contamination with tetra-through heptahalogenated dibenzo-p-dioxins or dibenzofurans.

Rationale: Polyhalogenated dibenzo-p-dioxins or dibenzofurans may be formed during manufacture of tetrachlorvinphos. The Agency has identified these contaminants as being toxicologically significant. The Agency does not have sufficient data to determine the extent and significance of the contamination.

14. Data Identified for Immediate Review

The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

Section 158.340 Toxicology

83-3 Teratology(Rat)- tolerance reassessment.

84-2 Mutagenicity (all studies)-

83-2 Oncogenicity-Rat onocogenicity risk assessment to applicators.

85-2 21-day Dermal-

Section 158.75 Requirement for Additional Data

--- Other Exposure Data (Dermal and Inhalation)- Oncogenicity risk assessment.

Section 158.240 Residue Chemistry

171-4 Animal Metabolism-Tiered study

Magnitude of the Residues in Fat and Milk-Tiered study.

Storage Stability-Tiered study.

Section 158.290 Environmental Fate

161-1	Hydrolysis-Analysis for ground water contamination potential.
162-1	Aerobic Soil Metabolism-Analysis for ground water contamination potential.
163-1	Leaching and Adsorption/Desorption-Analysis for ground water contamination potential.
164-6	Dissipation of Residues in Excrement Tiered study.

15. Continued Registration

While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing tetrachlorvinphos may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7).

Issuance of this Standard provides a mechanism for identifying data needs and labeling changes arising from available data. Required data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain tetrachlorvinphos, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the use patterns listed below. The EPA Index to Pesticide Chemicals (for availability, see page 1) lists all registered uses, as well as approved maximum application rates and frequencies.

-Terrestrial, non-food

-Indoor

-Domestic outdoor

D. LABELING

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing this pesticide may be released for shipment by the registrant after October 31, 1989, unless the product bears an amended label which complies with the requirements of this Standard. No pesticide product containing this pesticide may be distributed or sold after October 31, 1990 unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

ACTIVE INGREDIENT

Tetrachlorvinphos: 2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate............%

2. Use Pattern Statements

A. MANUFACTURING USE PRODUCTS

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

a. Labels for MPs must bear the following identifying phrase directly beneath the product name:

"An insecticide for formulating use only."

b. In the directions for use, the following statement must appear:

"Formulators using this product are responsible for obtaining EPA registration of their formulated product."

c. In the directions for use, the following statement regarding acceptable use patterns must appear:

"For formulation into end-use insecticide products intended only for (list acceptable sites)."

NOTE: No use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern.

d. If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

NOTE: The technical bulletin must be submitted with the product label for Agency review.

e. The following statements are required to appear under the "Environmental Hazards" heading:

"This pesticide is highly toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or the Regional Office of EPA."

B. END USE PRODUCTS

a. The ingredient statement for EPs must declare the active ingredient as:

Tetrachlorvinphos: 2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate......%

1. All products allowing for outdoor use must bear the following environmental hazards statements:

"This pesticide is toxic to fish. Drift and runoff may be hazardous to aquatic organisms in adjacent areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwater."

"This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

2. All products allowing for domestic outdoor use must bear the following environmental hazards statement:

"This pesticide is toxic to fish. Do not contaminate water when disposing of equipment washwaters."

3. The following protective clothing statements must appear on all products allowing for use on livestock, agricultural premises, feed additives:

For dusts and sprays: " Wear long-sleeved shirt and pants; chemical resistant gloves; shoes and socks." For ear tags: "wear gloves when applying tags."

4. The following protective clothing statements must appear on all products allowing domestic use:

For dusts and sprays: "Wear long-sleeved shirt and pants, shoes and socks."

5. All products allowing for use of tetrachlorvinphos as a feed additive and/or use on manure (droppings) must bear the following statement:

" Do not use manure/droppings on land where food crops are to be grown during the current growing season."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B.[3]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

---

[3] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption,[4] the data requirements listed in Table C.3.

If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

---

[4] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[5]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

---

[5] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will

submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the regis- tration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Tetrachlorvinphos Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

> Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.
>
> Table B contains product-specific data requirements that apply only to a manufacturing use product.
>
> Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not

have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 6 requires that data be submitted, this column indicates when the data are to be submitted, based on the date of receipt of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A

GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe For Data Submission-
Part 158, Subpart C, Product Chemistry						
Product Identity and Composition						
61-2 - Description of Starting Materials and Manufacturing Process	TGAI	All	No	N/A	Yes[2]	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	N/A	Yes[3]	9 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	No	N/A	Yes4	9 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	N/A	Yes[5]	9 Months
63-3 - Physical State	TGAI	All	No	N/A	Yes[5]	9 Months
63-4 - Odor	TGAI	All	No	N/A	Yes[5]	9 Months
63-5 - Melting Point	TGAI	All	No	N/A	Yes[5] 6	9 Months
63-6 - Boiling Point	TGAI	All	No	N/A	Yes[7]	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1] (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]/
Part 158, Subpart C, Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	N/A	Yes[5]	9 Months
63-8 - Solubility	TGAI or PAI	All	No	N/A	Yes[5]	9 Months
63-9 - Vapor Pressure	TGAI or PAI	All	No	N/A	Yes[5]	9 Months
63-10 - Dissociation Constant	TGAI or PAI	All	No	N/A	Yes[5]	9 Months
63-11 - Octanol/Water Partition Coefficient	PAI	All	No	N/A	Yes[5] 8	9 Months
63-12 - pH	TGAI	All	No	N/A	Yes[5] 9	9 Months
63-13 - Stability	TGAI	All	No	N/A	Yes[5]	9 Months
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Part 158, Subpart C, Product Chemistry - Footnotes

[1] Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

[2] Complete information must be provided regarding the nature and process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

[3] A detailed discussion of all impurities that are or may be present at >=0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

[4] Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation datd (accuracy and precision) must be submitted for each analytical method used. In addition, specific data have been required from registrants on June 15, 1987, regarding the identity of all halogenated dibenzo-p-dioxins and dibenzofurans occurring in each technical product, analytical methods for their detection and quantitation, and certification of limits of these contaminants.

[5] Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[6] Data required if the technical chemical is a solid at room temperature.

7 Data not required because technical tetrachlorvinphos products are solids at room temperature.

8 Data required if the technical product is organic and nonpolar.

[9] Data required if the test substance is dispersible in water.

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission-
Sec. 158.240 Residue Chemistry						
171-2 - Chemical Identity	TGAI	H, I	No		Yes[1]	
171-3 - Directions for Use		H, I	Yes	(See Use Index)	No	
171-4 - Nature of the Residue (Metabolism)						
- Plants	PAIRA	N/A	No		No[2]	
- Livestock	PAIRA	H, I	Partially	00116020, 00117354, 00120147, 00120204	Yes[3]	18 Months
171-4 - Residue Analytical Methods - Animal Residues	TGAI and metabolites	H, I	Partially	00038458, 00077812, 00077814, 00077816, 00115939, 00116020, 00116553, 00117329, 00117340, 00117351, 00117354, 00117389, 00118265, 00120147, 00120200, 00120205,	Yes[3,4]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.240 Residue Chemistry (cont'd)						
171-4 - Residue Analytical Methods - Animal Residues (cont'd)				00120206, 00120229, 00130705, 00133913, 05004211, 40530101		
171-4 - Storage Stability Data	PAI and Pure	H, I	Partially	00117329, 00117354, 00117361, 00117389, 00133913	Yes[5],[6]	18 Months
171-4 - Magnitude of the Residues						
- Magnitude of the Residues in Meat, Milk, Poultry, and Eggs						
- Fat of Cattle, Goats, Hogs, Horses, and Sheep	TGAI	H, I	Partially	00038458, 00115939, 00117298, 00117339, 00117354, 00117389,	Reserved [7]	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[1]
Sec. 158.240 Residue Chemistry (cont'd)						
171-4 - Magnitude of the Residues						
- Magnitude of the Residues in Meat, Milk, Poultry, and Eggs (Cont'd)						
- Fat of Cattle, Goats, Hogs, Horses, and Sheep (Cont'd)				00118265, 00120200, 00120206		
- Milk	TGAI	H, I	Partially	00117298, 00117354, 00117389, 00118265, 00120206, 05006630	Reserved [7]	
- Poultry Fat and Eggs	TGAI	H, I	Partially	00084189, 00117340, 00120225, 00120227	Reserved [7]	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Sec. 158.240 Residue Chemistry - Footnotes

1 Refer to Product Chemistry Data Requirements tables (A and B).

2 There are no plant uses currently registered for tetrachlorvinphos.

3 Metabolism studies reflecting direct animal treatments using cattle, poultry, and swine. Animals must be sprayed daily for 28 days and in separate tests, orally dosed for 3 days (cattle and swine only), using [^{14}C-ring] tetrachlorvinphos at a rate sufficiently high to permit adequate characterization of ^{14}C-residues in muscle, fat, liver, kidney, milk, and eggs. Eggs and milk must be collected twice daily throughout the treatment period and animals must be sacrificed within 24 hours of the final application or dosing. Representative samples from these tests must be analyzed using all current and proposed enforcement methods (including FDA multiresidue protocols I-IV and Method I in the PAM, Vol. II, Pest. Reg. Sec. 180.252) to ascertain that the methods are capable of accurately quantifying all residues of toxicological concern.

4 If metabolites of concern other than tetrachlorvinphos *per se* are found in the required metabolism studies, adequately validated methods for their detection, which may be used for data collection and tolerance enforcement, will be required.

5 The storage intervals and conditions of samples (including samples from previously submitted studies) used to support all established tolerances for residues of tetrachlorvinphos must be submitted. These data must be accompanied by data depicting the percent decline in residues of tetrachlorvinphos at the times and under the conditions specified. Additional stability studies are not required for milk fat stored at 0°C up to 31 days and animal fat stored at room temperature up to 11 days. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used.

6 The nature of the residue in animals has not been adequately described. If the requested metabolism studies indicate the presence of additional residues of toxicological concern in animal commodities, data depicting the stability of such residues in storage will be required.

7 On receipt of the requested animal metabolism data, the adequacy of the available data regarding the magnitude of the residue in animal products will be determined and, if necessary, additional data will be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	PAIRA	B, H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	PAIRA	B, H	No		Yes	12 Months
161-3 - On Soil	PAIRA	N/A	No		No[1]	
161-4 - In Air	PAIRA	N/A	No		No[1]	
Metabolism studies - Lab						
162-1 - Aerobic Soil	PAIRA	B, H	No		Yes	27 Months
162-2 - Anaerobic Soil	PAIRA	N/A	No		No[1]	
162-3 - Anaerobic Aquatic	PAIRA	N/A	No		No[1]	
162-4 - Aerobic Aquatic	PAIRA	N/A	No		No[1]	
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	PAIRA	B, H	No		Yes2	12 Months
163-2 - Volatility (Lab)	TEP	N/A	No		No[1]	
163-3 - Volatility (Field)	TEP	N/A	No		No[1]	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.290 Environmental Fate	(continued)					
Dissipation Studies - Field						
164-1 - Soil	TEP	B, H	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	N/A	No		No[1]	
164-3 - Forestry	TEP	N/A	No		No[1]	
164-4 - Combination and Tank Mixes	TEP	N/A	No		No[3]	
164-5 - Soil, Long-Term	TEP	N/A	No		Reserved[4]	
164-6 - Dissipation of Residues in Excrement	-	I	No		Reserved[5]	90-days fo Protocol 27 Months for Final Report
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	N/A	No		Reserved[5a]	
165-2 - Rotational Crops (Field)	TEP	N/A	No		No[5b]	
165-3 - Irrigated Crops	TEP	N/A	No		No[1]	
165-4 - In Fish	TGAI OR PAIRA	N/A	No		No[1]	
165-5 - In Aquatic Nontarget Organism	TEP	N/A	No		No[1]	

TABLE
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission-
Sec. 158.290 Environmental Fate (continued)						
Sec. 158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	N/A	No		No[1]	
132-2 - Soil Dissipation	TEP	N/A	No		No[1]	
132-3 - Dermal Exposure	TEP	N/A	No		No[1]	
132-4 - Inhalation Exposure	TEP	N/A	No		No1	
Sec. 158.75 Requirement for Additional Data						
- Other Exposure Data	TEP	B, H, I	No		Yes[6]	90-Days for Acceptable Protocol 18 Months for Final Report
Sec. 158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	N/A	No		No[1]	
202-1 - Drift Field Evaluation	TEP	N/A	No		No[1]	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Sec. 158.290 Environmental Fate - Footnotes
Sec. 158.390 Reentry Protection - Footnotes
Sec. 158.440 Spray Drift - Footnotes

1 Study not required based on the registered use patterns.

2 Batch equilibrium (adsorption/desorption) required for the domestic outdoor uses.

3 Combination and tank mixes are not being addressed in this Standard.

4 Long-term field dissipation data requirement is deferred pending receipt of acceptable field dissipation data (164-1). If required, the long-term field dissipation study will be due within 50 months after notification of the requirement by the Agency.

5 Analysis of manure (droppings) from the feed-additive use is required at zero time, 1 and 2 weeks, 3,4 and 6 months under feed lot conditions. Parent and degradate decline curve is also required.

5a Contingent on the findings of the residue analysis of excrement study.

5b Contingent on finding residues of concern in the confined crop rotation study.

6 Dermal and inhalation exposure data for mixer/loaders and/or applicators are required to support the feed additive use, large animal dust use, poultry house use, and general spray indoor and outdoor use (the registrant must choose at least one representative indoor and outdoor site from a list including agricultural premises, animal spray sites, recreational areas, and manure piles; the registrant should provide justification for choosing a particular site). Studies should be conducted according to the Agency's Pesticide Assessment Guidelines, Subdivision U, Applicator Monitoring. Protocals for conducting such studies must be submitted for Agency approval.

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Test Data Requirement	Use Substance	Dose EPA Patterns	Citation Have Data?	Bibliographic Must Additional (MRID)	for Data Be Submitted?	Timeframe Submission-
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TGAI	B, H, I	No		Yes	9 Months
81-2 - Acute Dermal - Rat	TGAI	B, H, I	No		Yes	9 Months
81-3 - Acute Inhalation - Rat	TGAI	B, H, I	Yes	00138933	No	
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	B, H, I	Yes	00077801	No	
Subchronic Testing						
82-1 - 90-Day Feeding -						
- Rodent	TGAI	H, I	Partially	00043487, 00120199	No[1]	
- Nonrodent	TGAI	H, I	Partially	00043488	No[2]	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.340 Toxicology (cont'd)						
Subchronic Testing (cont'd)						
82-2 - 21-Day Dermal	TGAI	B, H, I	No		Yes	12 Months
82-3 - 90-Day Dermal	TGAI	B, H, I	No		No[3]	
82-4 - 90-Day Inhalation	TGAI	B, H, I	No		No[3]	
82-5 - 90-Day Neurotoxicity	TGAI	B, H, I	No		No[4]	
Chronic Testing						
83-1 - Chronic Toxicity -						
- Rodent	TGAI	B, H, I	Yes	00112525	No	
- Nonrodent	TGAI	B, H, I	Yes	00077819	No	
83-2 - Oncogenicity -						
- Rat	TGAI	B, H, I	Yes	00117443	Yes[5,5a]	50 months
- Mouse	TGAI	B, H, I	Yes	00117443, 00126039	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.340 Toxicology (cont'd)						
Chronic Testing (cont'd)						
83-3 - Teratogenicity -						
- Rat	TGAI	H, I	Yes		Reserved[6]	
- Rabbit	TGAI	H, I	Yes	00127831	No	
83-4 - Reproduction	TGAI	H, I	Yes	00077802	No	
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	B, H, I	Partially	00072172	Yes	9 Months
84-2 - Chromosome Aberration	TGAI	B, H, I	Partially	00072171, 00082160	Yes	12 Months
84-2 - Other Mechanism of Mutagenicity	TGAI	B, H, I	No		Yes	12 Months
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	H, I	Partially	00077805	Yes	24 Months
85-2 - Domestic Animal Safety	EP	H, I	Partially		Reserved [7]	
85-3 - Dermal Absorption	PAI or PAIRA	H, I	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Sec. 158.340 Toxicology - Footnotes

1 This requirement is waived based on the submission of an acceptable chronic feeding study in the rat.

2 This requirement is waived based on the submission of an acceptable chronic feeding study in the dog.

3 Study not required based on the registered use patterns.

4 Since an acute neurotoxicity study in hens was negative this study is not required.

5 The Agency has determined that an additional oncogenicity study in rats is required. Available studies had design deficiencies (# of animals used was inadequate; use of pooled controls versus concurrent controls).

5a Registrant who conduct chronic feeding and/or oncogenicity studies should inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the Maximum Tolerated Dose observed in s or range finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being u chronic feeding and/or oncogenicity studies. If EPA subsequently determines that the study was conducted using a dosage rate that was too low to assess long-term effects, the study may be deemed not to satisfy the data requirements.

6 Data submitted in response to the December, 1984 Comprehensive Data Call-In were not received in time to be included in the reviewed for this Standard. Therefore, no determination has been made as to the adequacy of this data satisfying the data Should the data be found unacceptable after Agency review a new study will be required under Section 3(c)(2)(B).

7 The Agency has received adverse effects/incidents concerning the use of tetrachlorvinphos on domestic animals (dogs, cats and horses). The Agency is re-examining all studies concerning the toxicity and efficacy of this product to determine if additional data, labeling or other action is warranted regarding the continued registration of this product.

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.490 Wildlife and Aquatic Organisms						
Avian And Mammalian Testing						
71-1 - Avian Acute Oral Toxicity	TGAI	B, H, I[2]	Yes	00160000	No	
71-2 - Avian Subacute Dietary Toxicity	TGAI	B, H, I[2,3]	Yes	00022923	No	
71-3 - Wild Mammal Toxicity	TGAI	B, I	No		No[1]	
71-4 - Avian Reproduction	TGAI	B, I	No		No[1]	
71-5 - Simulated and Actual Field Testing for Mammals and Birds	TEP	B, I	No		No[1]	
Aquatic Organisms Testing						
72-1 - Freshwater Fish Acute Toxicity	TGAI	B, H, I[2,3]	Yes	40098001	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	B, H, I[2]	No		Yes	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.490 Wildlife and Aquatic Organisms (cont'd)						
Aquatic Organisms Testing (cont'd)						
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	B	No		No[1]	
	TEP	B	No		No[1]	
- Shrimp	TGAI	B	No		No[1]	
	TEP	B	No		No[1]	
- Oyster	TGAI	B	No		No[1]	
	TEP	B	No		No[1]	
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle						
- Freshwater	TGAI	B	No		No[1]	
	TEP	B	No		No[1]	
- Estuarine	TGAI	B	No		No[1]	
	TEP	B	No		No[1]	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.490 Wildlife and Aquatic Organisms (cont'd)						
Aquatic Organisms Testing (cont'd)						
72-5 - Fish Life Cycle	TGAI	B	No		No[1]	
	TEP	B	No		No[1]	
72-6 - Aquatic Organism Accumulation	TEP	B	No		No[1]	
72-7 - Simulated or Actual Field Testing						
- Aquatic Organisms	TEP	B	No		No[1]	

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Sec. 158.490 Wildlife and Aquatic Organisms - Footnotes

[1] Study not required based on the registered use patterns.

[2] Study required to support the manufacturing use product reformulated into end-use products.

[3] Only one species need be referenced.

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission
Sec. 158.590 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honeybee Acute Contact Toxicity	TGAI	B, H	Yes	00036935	No	
141-2 - Honeybee - Toxicity of Residues on Foliage	TEP	B, H	Yes	05000837	No	
141-4 - Honeybee Subacute Feeding Study	Reserved[1]					
141-5 - Field Testing for Pollinators	TEP	B, H	No		No[2]	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[3]					
142-2 - Aquatic Insect Life-cycle Study	Reserved[3]					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[3]					
NONTARGET INSECT TESTING - PREDATORS AND PARASITES						
143-1 thru 143-3 -	Reserved[3]					

TABLE A
GENERIC DATA REQUIREMENTS FOR TETRACHLORVINPHOS

Sec. 158.590 Nontarget Insects - Footnotes

[1] Reserved pending development of test methodology.

[2] Available data do not indicate the need for field testing.

[3] Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TETRACHLORVINPHOS

Data Requirement	Test Substance-	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation (MRID)[2]	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158, Subpart C, Product Chemistry						
Product Identity and Composition						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	N/A	Yes[2]	6 Months
61-2 - Description of Starting Materials and Manufacturing Process	MP	All	No	N/A	Yes[3]	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	N/A	Yes[4]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	MP	All	No	N/A	Yes[5]	12 Months
62-2 - Certification of Ingredient Limits	MP	All	No	N/A	Yes[6]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No	N/A	Yes[7]	12 Months

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TETRACHLORVINPHOS

Data Requirement	Test Substance-	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation (MRID)[2]	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158, Subpart C, Product Chemistry						
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	N/A	Yes[8]	6 Months
63-3 - Physical State	MP	All	No	N/A	Yes[8]	6 Months
63-4 - Odor	MP	All	No	N/A	Yes[8]	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	N/A	Yes[8]	6 Months
63-12 - pH	MP	All	No	N/A	Yes[8,9]	6 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	N/A	Yes[8,10]	6 Months
63-15 - Flammability	MP	All	No	N/A	Yes[8,11]	6 Months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TETRACHLORVINPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation (MRID)[2]	Must Additional Data Be Submitted?	Timeframe for Submission
Part 158, Subpart C, Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-16 - Explodability	MP	All	No	N/A	Yes[8,12]	9 Months
63-17 - Storage Stability	MP	All	No	N/A	Yes[8]	15 Months
63-18 - Viscosity	MP	All	No	N/A	Yes[8,13]	9 Months
63-19 - Miscibility	MP	All	No	N/A	Yes[8,14]	9 Months
63-20 - Corrosion Characteristics	MP	All	No	N/A	Yes[8]	15 Months
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	N/A	No[15]	

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TETRACHLORVINPHOS

Part 158. Subpart C. Product Chemistry - Footnotes

1 Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2 The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3 Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, Specific data have been required from registrants on 6/15/87 regarding the identity of all halogenated di-benzo-p-dioxins and dibenzofurans occurring in each technical product, analytical methods for their detection and quantitation, and and certification of limits of these contaminants.

4 A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5 Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

6 Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at $>0.1\%$ (w/w) and each "toxicologically significant" impurity present at $<0.1\%$ (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570 Rev. 2-85.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TETRACHLORVINPHOS

Part 158, Subpart C, Product Chemistry - Footnotes (continued)

[7] Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

[8] Physicochemical characteristics as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

[9] Data required if the test substance is dispersible in water.

[10] Data required if the product contains an oxidizing or reducing agent.

[11] Data required if the product contains combustible liquids.

[12] Data required if the product is potentially explosive.

[13] Data required if the product is a liquid.

[14] Data required if the product is a liquid and is to be diluted with petroleum solvents.

[15] If samples are needed, the Agency will request them.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TETRACHLORVINPHOS

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?	Bibliographic Citation (MRID)	Must Additional Data Be Submitted?	Timeframe for Submission[2]
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP	H, I	No		Yes	9 Months
81-2 - Acute Dermal - Rat	MP	H, I	No		Yes	9 Months
81-3 - Acute Inhalation - Rat	MP	H, I	Yes	00138933	No	
81-4 - Eye Irritation - Rabbit	MP	H, I	No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	MP	H, I	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	H, I	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	MP	H, I	Yes	00077801	No	

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING TETRACHLORVINPHOS

Sec. 158.340 Toxicology - Footnotes

1 Test material: MP = Manufacturing-Use Product.

2 Due dates refer to the number of months following the registrant's receipt of this Registration Standard, unless otherwise indicated.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final estabment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear
in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are not restricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant be qualified "Distributed
3	Net contents	All products	None	Bottom front panel or end of label text	May be in met U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in si parallel to o
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front pan must be group blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type siz
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type siz

SUMMARY-7

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'

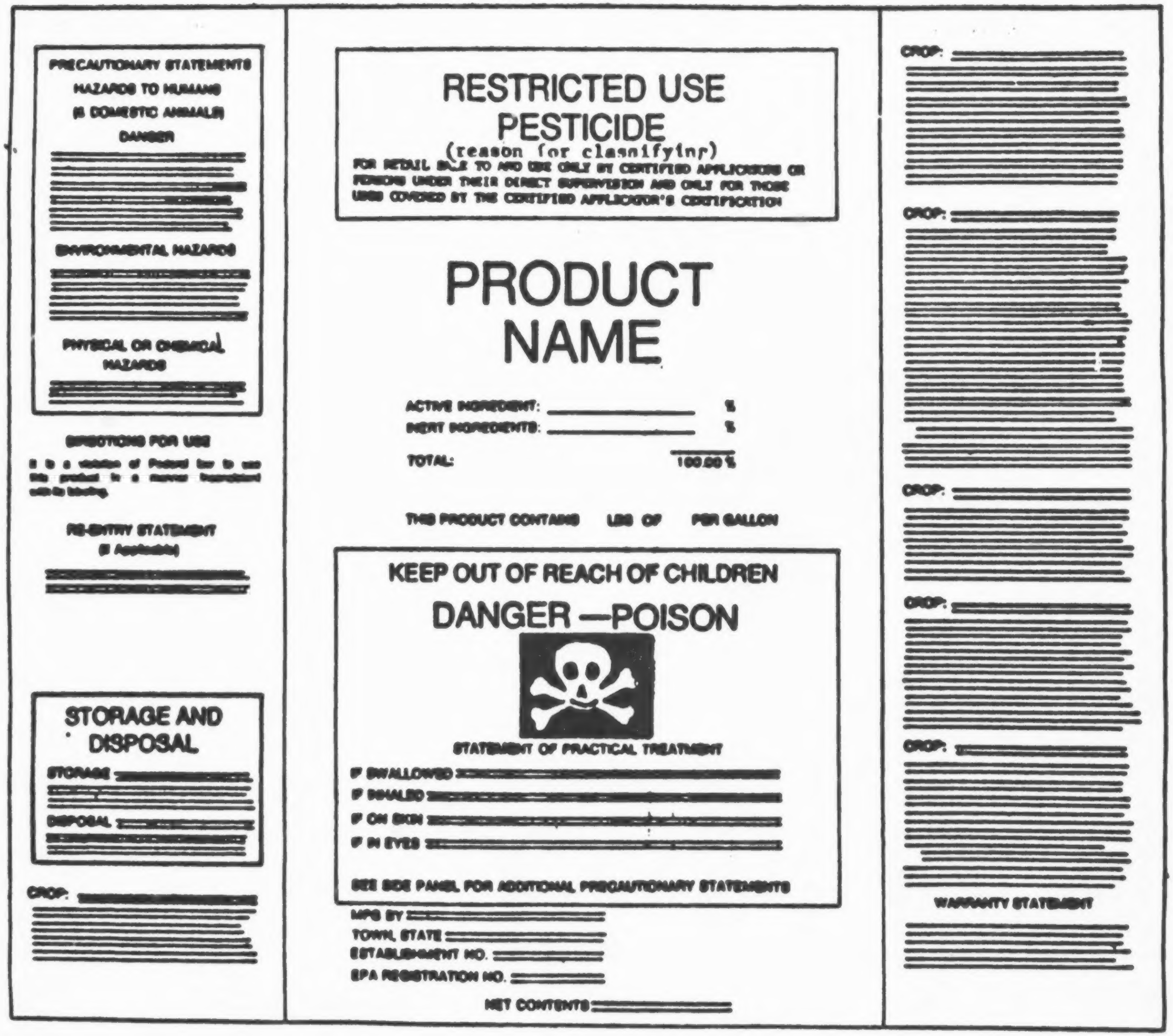
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be group 8A, 8B, and 8
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be prece word.
8B	Environmental hazards	All products	None	Same as above	Environmental caution where

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appe PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a st restriction. PESTICIDE" mu signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required stat "It is a v to use th inconsist
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set a guishable fro for use. Refer to Appe CONT/DIS, and information a
10C	Directions for use	All products	None	None	May be in met

Reproduced from best available copy.



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE
PESTICIDE
(reason for classifying)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT
NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS

CROP:

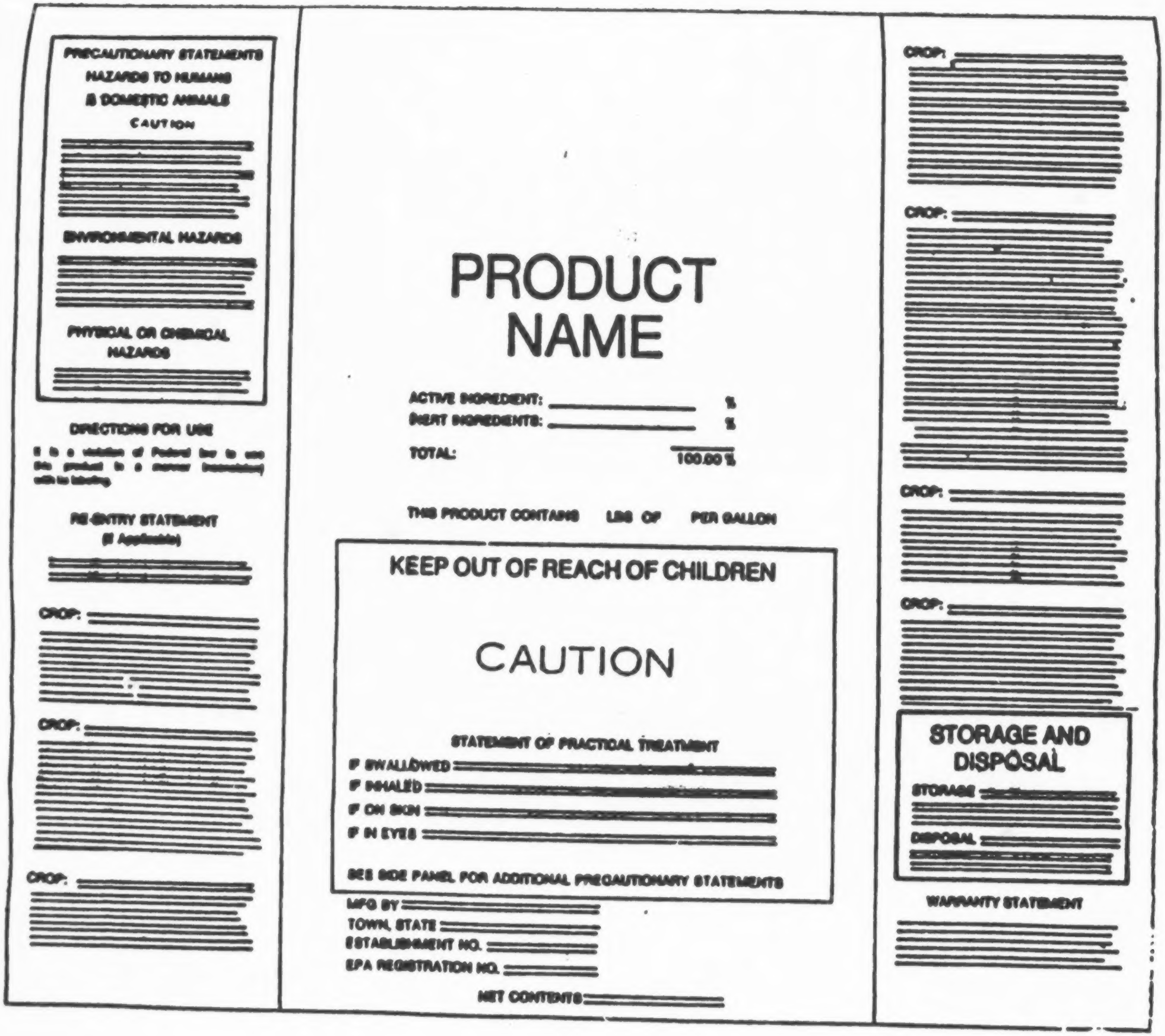
CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT


PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
RE-ENTRY STATEMENT
(If Applicable)
CROP:
CROP:
CROP:
PRODUCT
NAME
ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS
CROP:
CROP:
CROP:
CROP:
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
WARRANTY STATEMENT

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (c) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for

Reproduced from
best available copy.

scribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on

Reproduced from
best available copy.

the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points: Required signal word, all capitals	Points: "Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category: Oral, inhalation, or dermal toxicity	Precautionary statements by toxicity category: Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the

Reproduced from
best available copy.

hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975, 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1
STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tetrachlorvinphos Standard

MRID	CITATION
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00038458	Schultz, D.R.; Rawn, D.T.; DeKay, D.E. (1973) Residues of SD 8447 in Biopsy Fat Samples from Pigs Fed 400 and 800 PPM Stirofos in the Ration: TIR-26-005-73. (Unpublished study received Jun 27, 1980 under OH5269; prepared by Shell Development Co., submitted by Diamond Shamrock Agricultural Chemicals, Cleveland, Ohio; CDL:242780-G)
00038485	Piccirillo, V.J.; Smith, J.M. (19??) Toxicology: Summary and Evaluation. (Unpublished study received Jan 21, 1976 under 5G1566; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:095050-A)
00043487	Stevenson, D.E.; Ferrigan, L.W. (1965) The Sub-acute Toxicity of the Halophenyl vinyl phosphate Insecticide SD 8447 to Rats: Report No. R(T)-1-65. (Unpublished study received Feb 25, 1966 under unknown admin. no.; prepared by Shell Research, Ltd., England, submitted by Shell Chemical Co., Washington, D.C.; CDL: 107943-K)
00043488	Walker, A.I.T.; Hunter, C. (1965) The Sub-acute Oral Toxicity of the Halophenyl vinyl phosphate Insecticide SE 8447 to Dogs: Report No. R(T)-6-65. (Unpublished study received Feb 25, 1966 under unknown admin. no.; prepared by Shell Research, Ltd., England, submitted by Shell Chemical Co., Washington, D.C.; CDL: 107943-L)
00072171	Cripps, R.E.; Doak, S.; Whitebread, C.; et al. (1974) Toxicity Studies with Gardona: Effect of Gardona on Micro-organisms in the Host-mediated Assay and in vitro: Group Research Report TLGR.0066.74. (Unpublished study received Mar 30, 1979 under 201-407; prepared by Shell Research, Ltd., England, submitted by Shell Chemical Co., Washington, D.C.; CDL:237921-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tetrachlorvinphos Standard

MRID	CITATION
00072172	Dean, B.J.; Van der Pauw, C.L.; Stevenson, D.E. (1976) Toxicity Studies with Gardona: Dominant Lethal Assay in Male Mice after Single Oral Doses or 5 Daily Oral Doses of Gardona: Group Research Report TLGR.0069.76. (Unpublished study received Mar 30, 1979 under 201-407; prepared by Shell Research, Ltd., England, submitted by Shell Chemical Co., Washington, D.C.; CDL:237921-D)
00077801	Brown, V.K.; Ferrigan, L.W.; Hunter, C.G. (1965) Demyelination Studies with the Insecticide SD 8447: Tox 8/65. (Unpublished study received May 23, 1967 under 8G0665; prepared by Shell Research Ltd., England, submitted by Shell Chemical Co., Washington, D.C.; CDL:091166-L)
00077802	Eisenlord, G.; Loquvam, G.S.; Nemenzo, J.; et al. (1966) Results of Reproduction Study of Rats Fed Diets Containing SD 8447 Insecticide over Three Generations: Report No. 28. (Unpublished study received May 23, 1967 under 8G0665; prepared by Hine Laboratories, Inc., submitted by Shell Chemical Co., Washington, D.C.; CDL:091166-M)
00077805	Hutson, D.H.; Akintonwa, D.A.A.; Griffiths, M.H.; et al. (1966) The Metabolism of 2-Chloro-1-(2',4',5'-trichlorophenyl)vinyl Dimethyl Phosphate (SD 8447) in the Dog and Rat: Research Report R(T)-9-66. (Unpublished study received May 23, 1967 under 8G0665; prepared by Shell Research Ltd., England, submitted by Shell Chemical Co., Washington, D.C.; CDL:091166-P)
00077812	Shell Development Company (1966) Residue Determination of SD 8447 and Its Low-melting Isomer SD 13462 in Agricultural Crops: GLC Electron Capture Method. Analytical method MMS-71/66 dated Jan 21, 1966. (Unpublished study received May 23, 1967 under 8G0665; CDL:091166-AE)
00077814	Shell Development Company (1966) Residue Determination of SD 8447 and Its Low-melting Isomer SD 13462 in Agricultural Crops: GLC Phosphorus Detector Method. Analytical method MMS-80/66 dated Dec 1966. (Unpublished study received May 23, 1967 under 8G0665; CDL:091166-AG)
00077816	Shell Development Company (1967) Residue Determination of Acid Hydrolizable Conjugate Metabolites from SD 8447 Treated Crops: GLC Electron-capture method. Analytical method MMS-85/67 dated Apr 1967. (Unpublished study received May 23, 1967 under 8G0665; CDL:091166-AI)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tetrachlorvinphos Standard

MRID	CITATION
00077819	Doyle, R.L.; Teske, R.H.; Elsea, J.R. (1968) Two-year Dietary Administration of SD 8447 to Dogs: P-99A. (Unpublished study received Aug 17, 1968 under 9F0739; prepared by Hill Top Research, Inc., submitted by Shell Chemical Co., Washington, D.C.; CDL: 091273-A)
00082160	Dean, B.J.; Senner, K.R. (1974) Toxicity Studies with Gardona: Chromosome Studies on Bone Marrow Cells of Chinese Hamsters after Two Daily Oral Doses of Gardona: Group Research Report TLGR.0062.74. (Unpublished study received Feb 6, 1976 under 201-225; prepared by Shell Research, Ltd., England, submitted by Shell Chemical Co., Washington, D.C.; CDL:223348-D)
00084189	Ivey, M.C.; DeVaney, J.A.; Ivie, G.W. (1981) Residues of Stirofos (Rabon) in Eggs of Laying Hens Treated for Northern Fowl Mite Control by Dipping. (U.S. Dept. of Agriculture, Science and Education Administration, Agricultural Research, Veterinary Toxicology and Entomology Research Laboratory; unpublished study; CDL:245949-A)
00091657	Anderson, L.D.; Atkins, E.L., Jr. (1966) 1965 Research on the Effect of Pesticides on Honey Bees: Submitter 17923. (Unpublished study received Jan 18, 1968 under 3125-143; prepared by Univ. of California--Riverside, Entomology Dept., submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:005635-T)
00112525	Walker, A.; Hunter, C. (1967) The Oral Toxicity of the Halophenyl Vinyl Phosphate Insecticide Gardona (SD 8447): Two Year Oral Experiment in Rats: Research Report R(T)-9-67. (Unpublished study received Aug 17, 1968 under 9F0739; prepared by Shell Research Ltd., Eng., submitted by Shell Chemical Co., Washington, DC; CDL:091274-0)
00115939	Shell Chemical Co. (1972) Residue Data in Reply to EPA's July 10, 1972 Letter of Special Review for Ciovap EC Insecticide. (Compilation; unpublished study received Sep 20, 1972 under 201-244; CDL:000948-A)
00116020	Shell Chemical Co. (1970) Residue Data Developed from the Use of Dairy Cattle: Rabon. (Compilation; unpublished study received Jan 19, 1970 under 1F1090; CDL:090850-B)
00116553	Shell Chemical Co. (1971) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: Gardona. (Compilation; unpublished study received Oct 12, 1972 under 2F1281; CDL:091818-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tetrachlorvinphos Standard

MRID	CITATION
00117298	Miller, R.; Gordon, C. (19??) Effect of feeding Rabon to dairy cows over extended periods. Journal of Economic Entomology 66(1): 135-138. (Also in unpublished submission received Oct 17, 1973 under 201-359; submitted by Shell Chemical Co., Washington, DC; CDL:050006-G)
00117329	Shell Chemical Co. (1969) Gardona: Residues in Milk and Other Subjects. (Compilation; unpublished study received on unknown date under 9F0805; CDL:093114-C)
00117339	Shell Chemical Co. (1969) Residue Data Developed from the Use of Rabon on Livestock. (Compilation; unpublished study received Dec 13, 1970 under 1F1121; CDL:093431-C)
00117340	Shell Chemical Co. (1969) Residue Data for Rabon Metabolites in Chicken Tissues and Eggs from California. (Compilation; unpublished study received Dec 1, 1969 under 9F0835; CDL:093538-A)
00117351	Shell Chemical Co. (1971) Analytical Methods for the Determination of the Pesticide Chemical: Gardona. (Compilation; unpublished study received Aug 6, 1971 under 2F1187; CDL:093510-C)
00117354	Shell Chemical Co. (1973) Residue Data: SD-8447. (Compilation; unpublished study received Oct 17, 1973 under 201-359; CDL: 101173-A)
00117361	Shell Chemical Co. (1975) Rabon Oral Larvicide Self-fed Supplement: Label Application. (Compilation; unpublished study received Jul 22, 1975 under 201-392; CDL:220992-A)
00117389	Shell Chemical Co. (1978) Rabon: Residues in Tissue, Milk, and Fat of Cattle. (Compilation; unpublished study received Mar 30, 1979 under 201-407; CDL:237924-A)
00117443	U.S. National Institutes of Health (1978) Bioassay of tetrachlorvinphos for possible carcinogenicity. By National Cancer Institute, Div. of Cancer Cause and Prevention, Carcinogenesis Program, Carcinogen Bioassay and Program Resources Branch. Bethesda, MD: USNIH. (NCI-CG-TR-33; CAS No. 961-11-5; DHEW publication no. (NIH)78-833; published study; CDL:238926-A)
00118265	Tennessee (1975) Residue Data in Support of the Use of Rabon Insecticide Cattle Ear Tags. (Compilation; unpublished study received Apr 12, 1979 under TN 79/1; CDL:238024-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tetrachlorvinphos Standard

MRID	CITATION
00120147	Shell Chemical Co. (1967) Determination of Gardona Residues in Various Products. (Compilation; unpublished study received Jun 12, 1968 under 9F0739; CDL:091275-A)
00120199	Walker, A.; Hunter, C. (1968) The Toxicity of the alpha Isomer of the Halophenyl Vinyl Phosphate Insecticide Gardona: 13 Week Oral Experiment in Rats: Group Research Report TLGR.0022.68. (Unpublished study received Apr 27, 1969 under 9F0804; prepared by Shell Research Ltd., Eng., submitted by Shell Chemical Co., Washington, DC; CDL:091388-A)
00120200	Shell Chemical Co. (1968) The Residue Data Developed from Test Plots Including a Description of the Analytical Methods Used: Gardona Insecticide. (Compilation; unpublished study received Apr 27, 1969 under 9F0804; CDL:091388-B)
00120204	Shell Chemical Co. (1969) [Determination of Residues of SD 8447 and Rabon in Goats and Poultry]. (Compilation; unpublished study received Apr 27, 1969 under 9F0804; CDL:091387-A)
00120205	Shell Chemical Co. (1968) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: Rabon. (Compilation; unpublished study received Apr 26, 1969 under 9F0805; CDL:091389-A)
00120206	Shell Chemical Co. (1969) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: Rabon. (Compilation; unpublished study received Apr 26, 1969 under 9F0805; CDL:091390-A)
00120225	Yadava, C. (1969) An Investigation of the Toxicology and Residues of Rabon in Poultry. Doctoral dissertation, Univ. of Massachusetts. (Unpublished study received Oct 4, 1969 under 9F0835; submitted by Shell Chemical Co., Washington, DC; CDL:091439-C)
00120227	Shell Chemical Co. (1969) The Results of the Amount of Residues Remaining, Including a Description of the Analytical Method: Rabon. (Compilation; unpublished study received Oct 4, 1969 under 9F0835; CDL:091439-G)
00120229	Shell Chemical Co. (1969) Rabon Insecticide on Poultry. (Unpublished study received Oct 5, 1969 under 9F0835; CDL:091440-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tetrachlorvinphos Standard

MRID	CITATION
00126039	Hazleton Laboratories America, Inc. (1980) 103-week Chronic Feeding Study in Mice: SD-8447 and Original SD-8447. Final rept. (Unpublished study received Jul 31, 1980 under unknown admin. no.; submitted by Shell Chemical Co., Washington, DC; CDL: 242976-A; 242977)
00127831	Laveglia, J.; Killeen, J.; Ignatoski, J. (1982) A Teratology Study in Rabbits with DS-36779: Document No. 572-5TX-82-0007-003. (Unpublished study received Apr 13, 1983 under unknown admin. no.; submitted by Diamond Shamrock Agricultural Chemicals, Cleveland, OH; CDL:249988-A)
00130705	Ralston Purina Co. (1969) Residue Data Developed from the Use of Dairy Cattle. (Compilation; unpublished study received Jun 17, 1983 under 602-301; CDL:251028-A)
00133913	Shell Chemical Co. (1973) Summary--Residues: Toxicity of SD 8447 in Cattle and Other Mammals. (Compilation; unpublished study received Dec 20, 1974 under 4H5047; CDL:223244-B)
00138933	Coate, W.; Zoetis, T.; Hardy, R. (1983) Acute Inhalation Toxicity Study in Rats: Ralston Purina Residual Livestock Insecticide: Project No. 2200-105. Final rept. (Unpublished study received Jan 31, 1984 under 602-301; prepared by Hazleton Laboratories America, Inc., submitted by Ralston Purina Co., St. Louis, MO; CDL:252343-C)
00160000	Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p.
05000837	Johansen, C.A. (1972) Toxicity of field-weathered insecticide residues to four kinds of bees. Environmental Entomology 1(3):393-394.
05004211	Bowman, M.C.; Beroza, M. (1967) Temperature-programmed gas chromatography of 20 phosphorus-containing insecticides on 4 different columns and its application to the analysis of milk and corn silage. Journal of the Association of Official Analytical Chemists 50(6):1228-1236.
05006630	Oehler, D.D.; Eschle, J.L.; Miller, J.A.; Claborn, H.V.; Ivey, M.C. (1969) Residues in milk resulting from ultra-low-volume sprays of malathion, methoxychlor, coumaphos, ronnel, or Gardona for control of the horn fly. Journal of Economic Entomology 62(6):1481-1483.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tetrachlorvinphos Standard

MRID	CITATION
40098001	Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base 410 Chemicals and 66 Species of Fresh-Water Animals. US Fish & Wildlife Service; Resource Publication (160):1-36.
40152701	Ford,W.;Killeen, J. (1987) A Teratology Study in Rats with Technical Rabon: Project ID: 1019-003; 85-0074. Unpublished study prepared by Ricerca, Inc. in cooperation with Argus Research Laboratories, Inc. and Test Substance Analysis Laboratory. 298 p.

IV. FORMS APPENDICES

Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

OMB Approval No.
2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________________ Date______________________________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No.
2070-005
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No.____________________ Date____________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:______________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _______________ concerning a requirement for submission of "generic" data on the active

ingredient ______________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated__________________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _______________ and their registration number(s) is/are ____________________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:______________________________

(Signature

Dated: ____________________ ______________________________

(Typed)

EPA Form 8570-27